

**IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF GEORGIA
WAYCROSS DIVISION**

ELI LILLY AND COMPANY,

Plaintiff,

v.

GEORGIA WEIGHT LOSS &
AESTHETICS, LLC,

Defendant.

Case No. CV 523-087

**COMPLAINT FOR TRADEMARK INFRINGEMENT,
FALSE ADVERTISING, AND UNFAIR COMPETITION**

Plaintiff Eli Lilly and Company (“Plaintiff” or “Lilly”), by and through its undersigned attorneys, files its complaint against Georgia Weight Loss & Aesthetics, LLC (“Defendant”) for injunctive and monetary relief. Plaintiff alleges as follows, upon actual knowledge with respect to itself and its own acts, and upon information and belief as to all other matters.

INTRODUCTION

1. For more than 140 years, Lilly has worked tirelessly to develop and deliver trusted and innovative medicines that meet real patient needs.

2. One of Lilly’s innovative medicines is Mounjaro[®], the first and only GIP (glucose-dependent insulintropic polypeptide) and GLP-1 (glucagon-like peptide-1) receptor agonist approved to treat adults with type 2 diabetes. The active ingredient in Mounjaro[®] is tirzepatide, a polypeptide analogue that activates the GIP and GLP-1 receptors, which are natural incretin hormones involved in blood sugar control. The development of tirzepatide is an example of Lilly’s commitment to innovation for people living with chronic diseases such as diabetes.

3. Mounjaro[®] is the only product containing tirzepatide that has been approved by the U.S. Food & Drug Administration (the “FDA”). Lilly is also the only company authorized to use the trademark Mounjaro[®] to identify its products containing tirzepatide. On its Facebook page, Defendant promotes the sale of “Mounjaro.” The drugs Defendant is selling are not Mounjaro[®]. They are compounded drug products that purport to contain tirzepatide and that are not approved by the FDA.

4. This is an action brought pursuant to the Lanham Act, 15 U.S.C. §§ 1051 et seq., related state laws and the common law, arising out of Defendant’s infringement of Plaintiff’s rights in its Mounjaro[®] trademark and Defendant’s acts of false advertising and unfair competition.

**Lilly’s FDA-Approved Tirzepatide
Medicine, Mounjaro[®], and Registered Trademark**

5. Lilly uses the trademark “Mounjaro” (the “trademark,” or the “mark”) to identify and promote an FDA-approved drug having the active ingredient tirzepatide that Lilly markets and sells in the United States.

6. Mounjaro[®] is indicated for adults with type 2 diabetes as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus.

7. Mounjaro[®] is a prescription-only medicine that should only be prescribed in direct consultation with, and under the supervision of, a licensed healthcare professional.

8. Mounjaro[®] has been extensively studied in clinical trials and is FDA-approved for the treatment of patients with type 2 diabetes mellitus.

9. Lilly does not sell Mounjaro[®], its FDA-approved medicine containing tirzepatide, to Defendant, for resale or redistribution. Lilly does not sell or promote Mounjaro[®] for chronic weight management or weight loss.

10. Lilly first adopted and used the Mounjaro[®] mark at least as early as June 3, 2022, and has used the Mounjaro[®] mark continuously since that time. Lilly has extensively promoted, advertised, and marketed its prescription-only medicines bearing the Mounjaro[®] mark for the treatment of patients with type 2 diabetes mellitus in many different channels, directed both to physicians and other health care professionals and to consumers.

11. As a result of its use of the Mounjaro[®] mark, Lilly owns valuable common law and other rights in and to the Mounjaro[®] mark.

**Defendant's Trademark Infringement and False Advertising
in Connection With its Sale to Patients of Unapproved Compounded Drugs**

12. Defendant markets and sells to patients seeking to lose weight compounded drug products that purport to contain tirzepatide and that are not approved by the FDA (“Unapproved Compounded Drugs”).

13. On information and belief, the Unapproved Compounded Drugs sold by Defendant are made by compounding pharmacies, which deliver them to Defendant for administration or dispensing to patients.

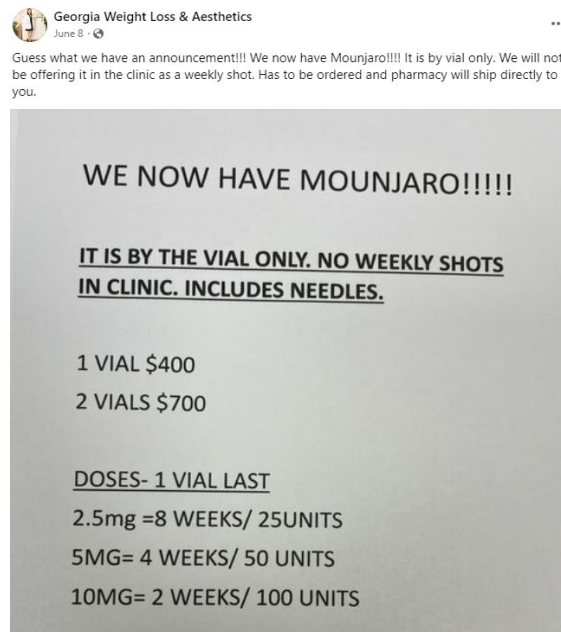
14. The FDA defines compounding as a “practice in which a licensed pharmacist, a licensed physician, or, in the case of an outsourcing facility, a person under the supervision of a licensed pharmacist, combines, mixes, or alters ingredients of a drug to create a medication tailored to the needs of an individual patient.” *See* <https://www.fda.gov/drugs/guidance-compliance-regulatory-information/human-drug-compounding>.

15. According to the FDA, “[c]ompounded drugs are not FDA-approved. This means that FDA does not review these drugs to evaluate their safety, effectiveness, or quality before they reach patients.”

16. The FDA has further stated that: “Compounded drugs . . . do not have the same safety, quality, and effectiveness assurances as approved drugs. Unnecessary use of compounded drugs unnecessarily exposes patients to potentially serious health risks. Because compounded drugs are not FDA-approved, FDA does not verify their safety, effectiveness or quality before they are marketed.”¹

17. Defendant uses Lilly’s Mounjaro[®] trademark to market and sell Unapproved Compounded Drugs purporting to contain “tirzepatide” that are not Mounjaro[®]. Defendant uses Lilly’s trademark to attract customers and generate revenues and profits, including by passing off as “Mounjaro” its own Unapproved Compounded Drugs purporting to contain tirzepatide and doing so for a use for which Mounjaro[®] is not approved, namely weight loss.

18. An example of Defendant’s unauthorized use of Lilly’s Mounjaro[®] trademark, in a June 8, 2023 post to Defendant’s Facebook page² is shown below:

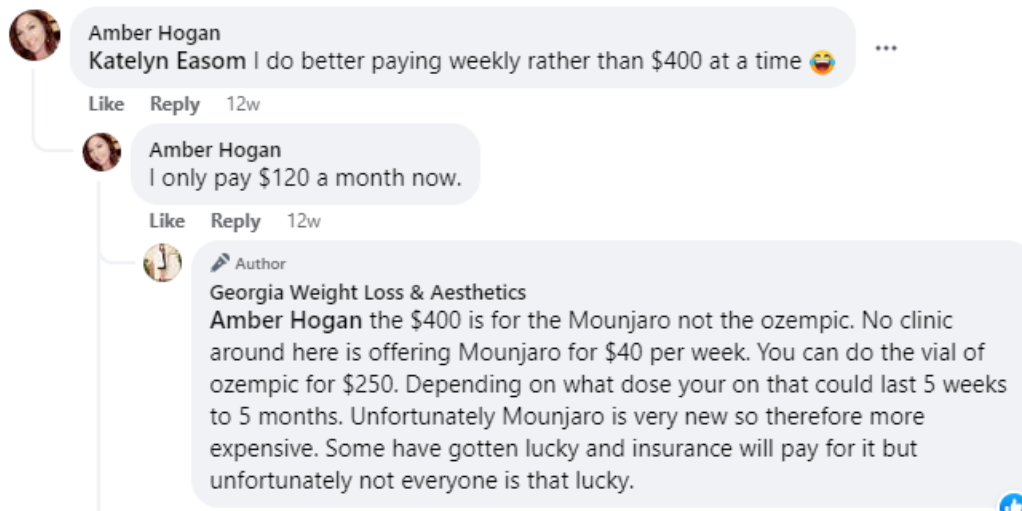


¹ Compounding and the FDA: Questions and Answers, <https://www.fda.gov/drugs/human-drug-compounding/compounding-and-fda-questions-and-answers>.

² Available at <https://www.facebook.com/profile.php?id=100063756030407>.

19. In this post, Defendant promotes its Unapproved Compounded Drugs as “Mounjaro.” And Defendant’s Facebook page conveys the unmistakable impression that Defendant is offering for sale injections of Lilly’s Mounjaro® medicine.

20. By way of further example, in a comment to its June 8, 2023 post, Defendant stated that the price of \$400 a vial it advertised was for “Mounjaro”:



21. Defendant first started using Lilly’s Mounjaro® mark to advertise its Unapproved Compounded Drugs after Lilly’s first use and registration of its Mounjaro® mark.

22. Defendant also falsely advertises its Unapproved Compounded Drugs on its Facebook page by making statements that claim or imply that its Unapproved Compounded Drugs are FDA-approved and/or subjected to clinical trials, including stating that the Unapproved Compounded Drugs “work[] just as good” as Mounjaro® and that Defendant “would never sell a drug that isn’t real,” thereby implying that Defendant’s drugs are equivalent to Mounjaro®, when they are not. For example, below is one of Defendant’s responses to the June 8, 2023 Facebook post excerpted above:



Author

Georgia Weight Loss & Aesthetics

Cindy Skipper Burke it is a compounded form. It comes from a pharmacy and is sent directly to you from the pharmacy. It works just as good. I would never sell a drug that isn't real. Won't risk my license dear.

23. Defendant continues to use the Mounjaro[®] mark, including in advertising and promotion on its Facebook page, in order to confuse and deceive customers who, upon information and belief, are seeking to buy but are in fact not buying genuine and FDA-approved Mounjaro[®] medicine.

24. Defendant's prominent and misleading use of the Mounjaro[®] mark is likely to confuse consumers and cause them to falsely believe that they are actually purchasing Mounjaro[®] medicine, that Defendant is a source for Lilly's FDA-approved medicine, and/or that Defendant's services are provided, licensed, sponsored, authorized, or approved by Lilly.

25. Defendant's use of the Mounjaro[®] mark is without the permission, consent or authorization of Lilly. Defendant has no right to use, and Defendant knows that it has no right to use, the Mounjaro[®] mark in connection with Defendant's Unapproved Compounded Drugs or otherwise.

26. Lilly has no control over the nature, quality or efficacy of the products sold by Defendant, including the Unapproved Compounded Drugs.

THE PARTIES

27. Plaintiff Lilly is a corporation organized and existing under the laws of Indiana and has its principal place of business in Indiana.

28. Plaintiff promotes, offers, and sells Mounjaro[®] throughout the United States, including in this District.

29. Defendant is a Georgia limited liability company with a principal place of business at 210 Peterson Avenue, S, Douglas, Georgia 31533, in this District. Defendant sells and promotes Unapproved Compounded Drugs masquerading as Mounjaro® and/or uses the Mounjaro® mark in its advertising and promotion of Unapproved Compounded Drugs that are not Mounjaro®.

JURISDICTION AND VENUE

30. The Court has subject matter jurisdiction over the Lanham Act causes of action pleaded herein pursuant to 35 U.S.C. § 1121 and 28 U.S.C. § 1338(a). The Court has supplemental jurisdiction over the state and common law causes of action pleaded herein pursuant to 28 U.S.C. § 1338(b).

31. Venue is proper in this District pursuant to 28 U.S.C. § 1391 because Defendant operates in this District, sells its Unapproved Compounded Drugs in this District, and otherwise conducts business in this District. Defendant is subject to personal jurisdiction in this District.

LILLY'S MOUNJARO® TRADEMARK

32. Plaintiff Lilly is the owner of U.S. trademark registration number 6,809,369, issued on August 2, 2022, for the mark MOUNJARO for pharmaceutical preparations for the treatment of diabetes, in International Class 5. A true and correct copy of Plaintiff Lilly's registration for the Mounjaro® mark is attached hereto as **Exhibit A**.

33. The Mounjaro® trademark is inherently distinctive.

34. Lilly promotes and advertises its Mounjaro® medicine to consumers and to physicians and licensed healthcare professionals, among others, through various channels, including on the website www.mounjaro.com, in social media, in online advertisements, and on television.

35. As a result of Lilly's use, promotion, and advertising of the Mounjaro[®] trademark and medicine, the Mounjaro[®] mark is exclusively associated with Plaintiff, serves to identify genuine Lilly products, and is a valuable asset of Lilly.

DEFENDANT'S INFRINGING USE OF THE MOUNJARO[®] MARK

36. Long after the filing date of Lilly's application to register the Mounjaro[®] trademark, after Lilly's first use of the Mounjaro[®] mark, and after Lilly secured federal registration for the Mounjaro[®] mark, Defendant started using the Mounjaro[®] mark in commercial advertising and promotion to promote its Unapproved Compounded Drugs in a false and misleading way. Examples of Defendant's trademark infringement and false advertising are shown above and are attached hereto as **Exhibit B**.

37. Describing Defendant's Unapproved Compounded Drugs as "Mounjaro" is a literally false statement because Defendant's drugs are not Mounjaro[®].

38. Defendant's advertising and promotional materials are false and misleading, suggesting and/or stating an association with Plaintiff's FDA-approved Mounjaro[®] medicine, when no such association exists.

39. There is no need for Defendant to use the Mounjaro[®] trademark to advertise or promote its Unapproved Compounded Drugs purporting to contain tirzepatide, other than to trade upon the reputation of Plaintiff and to create confusion in the marketplace and/or mislead the public regarding the origin, identity or source of Defendant's Unapproved Compounded Drugs.

40. Defendant's unauthorized use of the Mounjaro[®] trademark is likely to cause confusion, to cause mistake, or to deceive, and infringes Plaintiff's established exclusive rights in the trademark.

41. Upon information and belief, unless enjoined by this Court, Defendant will continue to use the Mounjaro[®] mark and/or otherwise falsely advertise its products as associated with or being Mounjaro[®], all in violation of Plaintiff's rights.

FIRST CAUSE OF ACTION

Trademark Infringement in Violation of 15 U.S.C. § 1114(1)

42. Plaintiff realleges and incorporates by reference each of the allegations contained in the foregoing paragraphs of this Complaint as though fully set forth here.

43. The Mounjaro[®] mark is an inherently distinctive, strong, valid, and protectable trademark owned by Plaintiff.

44. Plaintiff's trademark registration for its Mounjaro[®] mark constitutes *prima facie* evidence of the validity of the mark, of Plaintiff's registration and ownership of the mark, and of Plaintiff's exclusive right to use the mark in commerce on or in connection with the goods identified in the registration.

45. By virtue of its prior use and registration, Plaintiff has priority over Defendant with respect to the use of the Mounjaro[®] mark for pharmaceutical preparations sold in the United States.

46. Defendant uses the Mounjaro[®] mark in connection with the sale, advertising, and promotion of Unapproved Compounded Drugs purporting to contain tirzepatide, and uses the Mounjaro[®] mark to promote uses of tirzepatide for which Mounjaro[®] is not approved, namely weight loss.

47. Defendant's use in commerce of the Mounjaro[®] mark is likely to cause confusion, to cause mistake, or to deceive with respect to Plaintiff's identical mark.

48. The above-described acts of Defendant constitute infringement of a registered trademark in violation of Section 32(1) of the Lanham Act, 15 U.S.C. § 1114(1), entitling Plaintiff to relief.

49. Defendant has unfairly profited from its trademark infringement.

50. By reason of Defendant's acts of trademark infringement, Plaintiff has suffered damage to the goodwill associated with its Mounjaro[®] mark.

51. Defendant's acts of trademark infringement have irreparably harmed and, if not enjoined, will continue to irreparably harm Plaintiff, its federally-registered Mounjaro[®] trademark and the valuable goodwill associated with that trademark.

52. Defendant's acts of trademark infringement have irreparably harmed, and if not enjoined, will continue to irreparably harm the interests of the public in being free from confusion, mistake, and deception.

53. By reason of Defendant's acts, Plaintiff's remedies at law are not adequate to compensate for the injuries inflicted by Defendant. Accordingly, Plaintiff is entitled to preliminary and permanent injunctive relief pursuant to 15 U.S.C. § 1116.

54. By reason of Defendant's willful acts of trademark infringement, Plaintiff is entitled to an increased award of Defendant's profits under 15 U.S.C. § 1117.

55. This is an exceptional case, making Plaintiff eligible for an award of attorneys' fees under 15 U.S.C. § 1117.

SECOND CAUSE OF ACTION

Trademark Infringement, Use of False Designations of Origin and Unfair Competition in Violation of 15 U.S.C. § 1125(a)(1)(A)

56. Plaintiff realleges and incorporates by reference each of the allegations contained in the foregoing paragraphs of this Complaint as though fully set forth here.

57. Defendant uses the Mounjaro[®] mark in commerce in connection with Defendant's goods and services and in commercial advertising and promotion of its goods and services.

58. Defendant uses the Mounjaro[®] mark in commerce in a manner that is likely to cause confusion, or to cause mistake, or to deceive the relevant public into believing that Defendant's goods or services are authorized, sponsored, approved by, or otherwise affiliated with Plaintiff, with Plaintiff's genuine Mounjaro[®] medicine that is not approved for weight loss, and/or with the Mounjaro[®] mark.

59. The above-described acts of Defendant constitute infringement of the Mounjaro[®] mark and use of false designations of origin in violation of Section 43(a)(1)(A) of the Lanham Act, 15 U.S.C. § 1125(a)(1)(A), entitling Plaintiff to relief.

60. Defendant has unfairly profited from the actions alleged.

61. By reason of the above-described acts of Defendant, Plaintiff has suffered damage to the goodwill associated with the Mounjaro[®] trademark.

62. The above-described acts of Defendant have irreparably harmed and, if not enjoined, will continue to irreparably harm Plaintiff, the Mounjaro[®] trademark, and the valuable goodwill associated with the trademark.

63. The above-described acts of Defendant have irreparably harmed and, if not enjoined, will continue to irreparably harm the interest of the public in being free from confusion, mistake, and deception.

64. By reason of Defendant's acts, Plaintiff's remedies at law are not adequate to compensate for the injuries inflicted by Defendant. Accordingly, Plaintiff is entitled to preliminary and permanent injunctive relief pursuant to 15 U.S.C. § 1116.

65. Because the above-described acts of Defendant are willful, Plaintiff is entitled to an increased award of Defendant's profits under 15 U.S.C. § 1117.

66. This is an exceptional case, making Plaintiff eligible for an award of attorneys' fees under 15 U.S.C. § 1117.

THIRD CAUSE OF ACTION

False and Misleading Advertising and Promotion in Violation of 15 U.S.C. § 1125(a)(1)(B)

67. Plaintiff realleges and incorporates by reference each of the allegations contained in the foregoing paragraphs of this Complaint as though fully set forth here.

68. Defendant's practices, as described in this Complaint, constitute unfair competition and false advertising in violation of Section 43(a)(1)(B) of the Lanham Act, 15 U.S.C. § 1125(a)(1)(B).

69. Defendant has violated the Lanham Act by using false or misleading descriptions of fact and false or misleading representations of fact in its commercial advertising or promotion that misrepresent the nature, characteristics, and/or qualities of Defendant's business practices and products, as set forth above.

70. As set forth above, Defendant makes numerous false and/or misleading statements on its Facebook page, including that it is offering for sale "Mounjaro," and that its Unapproved Compounded Drugs "work[] just as good" as Lilly's Mounjaro[®] medicine.

71. Defendant's statements falsely imply that Defendant's Unapproved Compounded Drugs are Mounjaro[®] and/or are FDA-approved, which they are not.

72. The above-described acts of Defendant, if not enjoined by this Court, are likely to deceive members of the general public.

73. The above-described acts of Defendant have irreparably harmed and, if not enjoined, will continue to irreparably harm Plaintiff.

74. The above-described acts of Defendant have irreparably harmed and, if not enjoined, will continue to irreparably harm the interest of the public in being free from confusion, mistake, and deception.

75. By reason of Defendant's acts as alleged above, Plaintiff has suffered and will continue to suffer injuries, including injury to Plaintiff's business reputation. However, Plaintiff's remedies at law are not adequate to compensate for all the injuries inflicted by Defendant. Accordingly, Plaintiff is entitled to preliminary and permanent injunctive relief requiring Defendant to cease its false and misleading advertising and promotion and unfair competitive practices.

76. Because the above-described acts of Defendant are willful, Plaintiff is entitled to an increased award of Defendant's profits under 15 U.S.C. § 1117.

77. This is an exceptional case, making Plaintiff eligible for an award of attorneys' fees under 15 U.S.C. § 1117.

FOURTH CAUSE OF ACTION

Georgia Common Law Unfair Competition

78. Plaintiff realleges and incorporates by reference each of the allegations contained in the foregoing paragraphs of this Complaint as though fully set forth here.

79. The above-described acts of Defendant constitute common law unfair competition and trademark infringement in violation of Georgia common law.

80. The above-described acts of Defendant unfairly and wrongfully exploit Plaintiff's trademark, goodwill and reputation.

81. By reason of the above-described acts of Defendant, Plaintiff has suffered damage to its business reputation and the goodwill associated with the Mounjaro® trademark.

82. The above-described acts of Defendant have irreparably harmed and, if not enjoined, will continue to irreparably harm Plaintiff and the Mounjaro® trademark.

83. The above-described acts of Defendant have irreparably harmed and, if not enjoined, will continue to irreparably harm the interest of the public in being free from confusion, mistake, and deception.

84. By reason of Defendant's acts, Plaintiff's remedies at law are not adequate to compensate for the injuries inflicted by Defendant. Accordingly, Plaintiff is entitled to preliminary and permanent injunctive relief, in addition to monetary relief such as disgorgement of Defendant's profits, and corrective advertising costs.

FIFTH CAUSE OF ACTION

Violation of Georgia Uniform Deceptive Trade Practices Act, O.C.G.A. § 10-1-370, et seq.

85. Plaintiff realleges and incorporates by reference each of the allegations contained in the foregoing paragraphs of this Complaint as though fully set forth here.

86. The above-described acts of Defendant constitute unfair methods of competition, and/or unconscionable, deceptive, or unfair acts or practices in violation of the laws of the State of Georgia, including the Georgia Uniform Deceptive Trade Practices Act, O.C.G.A. §§ 10-1-370, et seq.

87. The Georgia Uniform Deceptive Trade Practices Act is designed to prevent any deceptive trade practice that "[c]auses likelihood of confusion or of misunderstanding as to the source, sponsorship, approval, or certification of goods or services," *see* O.C.G.A. § 10-1-

372(a)(2), or that “[c]auses likelihood of confusion or of misunderstanding as to affiliation, connection, or association with or certification by another.” *See* O.C.G.A. § 10-1-372(a)(3).

88. The above-described acts of Defendant are made in the conduct of Defendant’s business, trade or commerce.

89. The above-described acts of Defendant wrongfully exploit Plaintiff’s trademark in a manner likely to deceive the public and mislead reasonable consumers.

90. The above-described acts of Defendant have irreparably harmed and, if not enjoined, will continue to irreparably harm Plaintiff and its Mounjaro[®] trademark.

91. The above-described acts of Defendant have irreparably harmed and, if not enjoined, will continue to irreparably harm the interest of the public in being free from confusion, mistake, and deception.

92. Members of the public are also likely to suffer injury from the above-described acts of Defendant by purchasing a drug that they believe to be Plaintiff’s FDA-approved medicine, Mounjaro[®], not an Unapproved Compounded Drug that does not have the same safety, quality, and effectiveness assurances as FDA-approved drugs.

93. By reason of the above-described acts of Defendant, Plaintiff has suffered damage to its business reputation and to the goodwill associated with its trademark.

94. By reason of Defendant’s acts, Plaintiff’s remedy at law is not adequate to compensate for the injuries inflicted by Defendant. Accordingly, Plaintiff is entitled to entry of preliminary and permanent injunctive relief.

REQUEST FOR RELIEF

WHEREFORE, Plaintiff requests judgment against Defendant as follows:

1. That the Court enter a judgment against Defendant that Defendant has:

- a. Infringed the rights of Plaintiff in its federally-registered Mounjaro[®] mark, in violation of 15 U.S.C. § 1114(1);
 - b. Infringed the rights of Plaintiff in the Mounjaro[®] mark and engaged in unfair competition, in violation of 15 U.S.C. § 1125(a);
 - c. Engaged in false and misleading advertising and promotion, in violation of 15 U.S.C. § 1125(a);
 - d. Engaged in unfair competition and trademark infringement under the common law of Georgia and the Georgia Uniform Deceptive Trade Practices Act.
2. That each of the above acts was willful.
3. That the Court preliminarily and permanently enjoin and restrain Defendant and its agents, servants, employees, successors and assigns, and all other persons acting in concert with or in conspiracy with or affiliated with Defendant, from:
 - a. Using the trademark Mounjaro[®] or any mark confusingly similar to it, in connection with the advertising, promoting, marketing, selling or offering for sale of any goods or services (including, but not limited to, Unapproved Compounded Drugs) or otherwise engaging in any activity that is likely to cause confusion, cause mistake or deceive or otherwise infringes any rights of Plaintiff in and to the Mounjaro[®] mark or any similar mark;
 - b. Falsely stating or suggesting that Defendant's Unapproved Compounded Drugs are genuine Mounjaro[®], that Defendant is associated or connected in any way with Plaintiff or its products, or that

Defendant's Unapproved Compounded Drugs are approved by the FDA, have been the subject of clinical studies, or achieve certain therapeutic outcomes;

- c. Engaging in any unfair competition with Plaintiff; and
- d. Engaging in any deceptive acts.

4. Requiring Defendant, its agents, servants, employees, successors and assigns, and all other persons acting in concert with or in conspiracy with or affiliated with Defendant, to engage in corrective advertising by informing consumers that Defendant is not and never has been authorized by, affiliated with, sponsored by, approved by, or related to Plaintiff or genuine Mounjaro[®] medicine, that Defendant's product is not "Mounjaro," and that Defendant's Unapproved Compounded Drugs are not and have never been genuine Mounjaro[®] products or approved by the FDA.

5. That Plaintiff be awarded monetary relief, in the form of an award of Defendant's profits, for Defendant's trademark infringement, false advertising and unfair competition, and that this monetary relief be increased due to Defendant's willfulness, in accordance with the provisions of 15 U.S.C. § 1117 and any applicable state laws.

6. That Defendant be ordered to account for and disgorge to Plaintiff all amounts by which Defendant has been unjustly enriched by reason of Defendant's unlawful actions.

7. That Plaintiff be awarded punitive damages by reason of Defendant's willful unlawful actions.

8. For pre-judgment and post-judgment interest on all damages.

9. That the Court award Plaintiff its reasonable attorneys' fees pursuant to 15 U.S.C. § 1117, the Georgia Uniform Deceptive Trade Practices Act, and any other applicable provision of law.

10. That the Court award Plaintiff the costs of suit incurred herein.

11. For such other or further relief as the Court may deem just and proper.

Dated: September 19, 2023

Respectfully submitted,

KING & SPALDING LLP

s/ Charles Spalding, Jr.

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